

Appln. No. 10/825,472  
Response to Office Action of November 28, 2006

Docket No. 98204.00024

**REMARKS**

This response addresses the Office Action dated, November 28, 2006. Currently, claims 1-17 stand rejected.

**I. 35 U.S.C. § 112, FIRST PARAGRAPH**

The Examiner has rejected claims 1-17 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states that one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus which comprises the genus of derivatives of the carrier and the linker.

As an initial matter, Examiner's statement that the specification only discloses a "single species of the claimed genus disclosed that is within the scope of the claimed genus..." is erroneous. Applicant directs the Examiner to Example 2, which contains data resulting from the carrier-linker-peptide combination comprising the Nef<sub>(66-97)</sub> peptide.

Additionally, the analysis of whether the specification complies with the written description requirement is conducted from the standpoint of one of skill in the art at the time the application was filed and should include a determination of the field of the invention and the level of skill and knowledge in the art. Wang Labs. v. Toshiba Corp., 993 F.2d 858, 865 (Fed. Cir. 1993). Generally, the more sophisticated that a person of skill in the art would be, the less disclosure necessary to satisfy the written description requirement. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. In other words, information which is well known in the art need not be described in detail in the specification. See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80 (Fed. Cir. 1986).

Moreover, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 541 F.2d 257, 263 (CCPA 1976). Consequently, rejection of an original claim for lack of written description should be rare. As explained by the Federal Circuit, "(1) examples are not necessary to support the ade-

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quacy of a written description; (2) the written description standard may be met ... even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." Falkner v. Inglis, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006).

A person of ordinary skill in the art of biochemistry or pharmaceutical formulations would readily understand that the entire genus, encompassing the carrier and linker chemical moieties recited in the claim and their derivatives, was in the possession of the inventors at the time of the invention. The term "derivative" is intended to carry its plain and ordinary meaning which is widely understood by those of skill in the art as a compound derived or obtained from another and containing essential elements of the parent substance. For example, Merriam-Webster defines a chemical derivative as "a chemical substance related structurally to another substance and theoretically derivable from it" or "a substance that can be made from another substance." © 2006-2007 Merriam-Webster Online Dictionary. These definitions, which would be readily apparent to a person of ordinary skill in this sophisticated art, encompass the specific compounds recited in the claim and those that contain structural features common to the parent substance.

This situation is similar to the one presented to the Federal Circuit in Abraxis Bioscience v. Mayne Pharma, 467 F.3d 1370, 1376 (Fed. Cir. 2006). In Abraxis, the patentee's claims recited a chemical compound and derivatives thereof. The lower court defined derivatives as compounds synthesized from a lead compound by one or more chemical reactions. AstraZeneca v. Mayne Pharma, 352 F.Supp.2d 403, 414 (S.D.N.Y. 2004). On appeal, the Federal Circuit did not dispute that one of ordinary skill in the art would appreciate what was encompassed by the term derivatives, only that the patentee was not entitled to the full range of derivatives because in the specification the patentee limited himself to a particular category of derivatives. Abraxis, 467 F.3d at 1376.

Therefore, Applicant maintains that the specification provides adequate disclosure to allow persons of ordinary skill in the art to recognize that Applicants were in possession of the entire scope of what is claimed. As such, the Applicant respectfully requests that the Examiner withdraw this grounds for rejection.

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Notwithstanding the above, Applicant also submits new claim 25. New claim 25 contains the limitation that a carrier comprise "a chemical moiety selected from the group consisting of a cinnamoyl, a benzoyl, a phenylacetyl, a 3-OH-cinnamoyl, a 3,4-OH-cinnamoyl, a 3,4-methylenedioxycinnamoyl, a 3-methoxycinnamoyl, a 3,4-dimethoxycinnamoyl, a 3,4,5-trimethoxy-cinnamoyl, a *t*-butoxy-carbonyl, a benzyloxycarbonyl, a pivaloyl, a N-9-fluorenylethoxycarbonyl, and a fumaroyl." In addition, new claim 25 contains the limitation that a linker comprise "a chemical moiety selected from the group consisting of a C6 to C16 lipidic chains, a 8-amino-3,6-dioxaoctanoic acid and polymers thereof, a natural peptide, a pseudopeptide of less than 4 residues, a peptide mimic of less than 4 residues and combinations thereof." The new claim contains no new matter and is fully supported and enabled by the specification.

## II. 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner has rejected claims 1-17 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner states that the phrase "and derivatives thereof" for the genus of a Carrier and Linker is vague and indefinite.

The MPEP provides that definiteness of claim language must be analyzed in light of the content of the particular application disclosure; the teachings of the prior art; and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP § 2173.02. As interpreted by the Federal Circuit, the requirement to "distinctly" claim means that the claim only needs to be discernible to one of ordinary skill in the art. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1366 (Fed. Cir. 2004) (a claim should only be declared indefinite when it "remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction...."). Accordingly, a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. Bancorp Services, L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1372 (Fed. Cir. 2004).

Moreover, the claims need only provide a reasonable degree of particularity and distinctness to comply with the provisions of 35 U.S.C. § 112, second paragraph. MPEP § 2173.02. The Federal Circuit has held that if the scope of the subject matter embraced by the

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claims is reasonably clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971).

Applicant incorporates the comments from section I, herein, as though expressly set forth.

The instant specification and claims make reasonably clear that the chemical moieties encompassed by the claims are limited to those recited in the claims and derivatives of those chemical compounds recited in the claims. As previously discussed, a person of ordinary skill in the art would readily recognize and appreciate the meaning of, and what is encompassed by the term "derivatives." As such, the metes and bounds of the claims would be readily apparent to a person of ordinary skill in the art from reading the present disclosure and claims.

In view of the comments presented above, Applicant believes that this grounds for rejection has been adequately traversed. Therefore, Applicant respectfully requests that Examiner withdrawn this grounds of rejection.

### III. 35 U.S.C. § 101, DOUBLE PATENTING

The Examiner has rejected claims 1-17 under 35 U.S.C. § 101, double patenting, as claiming the same invention as that of claims 1, 3, 7, and 9-14 of USPN 6,908,900.

The MPEP provides that "a reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist." MPEP § 804.

Applicant submits that the instant claims recite at least one embodiment that would infringe the present claims but which would not infringe the claims of USPN 6,908,900, and therefore, statutory double patenting, i.e., 35 U.S.C. § 101, double patenting, does not exist in this case. For example, a composition comprising a 3-OH-cinnamoyl carrier moiety, a C6 linker, and a 10 amino acid peptide would not literally infringe claim 1 of USPN 6,908,900. In yet

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another example, a composition comprising a 3,4-OH-cinnamoyl carrier moiety, a C6 linker, and a 10 amino acid peptide would also not literally infringe claim 1 of USPN 6,908,900. In still another example, a composition comprising a 3,4,5-trimethoxy-cinnamoyl derivative carrier moiety, a C6 linker, and a 10 amino acid peptide would additionally not literally infringe claim 1 of USPN 6,908,900.

Therefore, Applicant submits that there statutory double patenting does not exist in the instant application. As such, the Applicant respectfully requests that Examiner withdraw this grounds for rejection.

#### IV. 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-17 under 35 U.S.C. § 102(b) as being anticipated by Li, USPN 6,136,952. The Examiner states that Li teaches various molecules can be attached to a JAGGED polypeptide including, for example, other polypeptides or chemical moieties. Specifically, the Examiner points to the following language at Col. 8, lines 24-26 of the Li patent, “various molecules can be attached to a JAGGED polypeptide including, for example, other polyptpides, carbohydrates, lipids, or chemical moieties....”

In order to anticipate a claim under 35 U.S.C. §102, all of the limitations of the claim must be disclosed in a single prior art reference. MPEP § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988). Moreover, the single source must disclose all of the claimed elements “*arranged as in the claim.*” *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). In addition, the disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

Li shows a biologically active peptide. In addition, at Col. 8, lines 24-26 Li indicates that included in its definition of JAGGED polypeptides are “minor modifications” (Col. 8, line 12) of the primary amino acid sequence.

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Li fails not only to teach every element of the claimed invention but also fails to teach every element "arranged as in the claim" of the present application. The present claim recites a peptide linked to a carrier and a linker. The peptide is a peptide having the formula  $aa_n$  where n is an integer  $\leq 40$ ; the carrier is a member selected from the group consisting of cinnamoyl, benzoyl, phenylacetyl, 3-OH-cinnamoyl, 3,4-OH-cinnamoyl, 3,4-methylenedioxycinnamoyl, 3-methoxycinnamoyl, 3,4-dimethoxycinnamoyl, 3,4,5-trimethoxy-cinnamoyl, *t*-butoxy-carbonyl, benzyloxycarbonyl, pivaloyl, N-9-fluorenylethoxycarbonyl, fumaroyl and derivatives thereof; and the linker is a member selected from the group consisting of C6 to C16 lipidic chains and derivatives thereof, 8-amino-3,6-dioxaoctanoic acid and polymeric derivatives thereof, natural peptides, pseudopeptides of less than 4 residues, peptide mimics of less than 4 residues and combinations thereof. Li does not disclose nor does it enable use of a carrier or linker. Li also does not disclose nor does it enable any of the presently claimed carrier or linker moieties. Moreover, Li does not teach, suggest, or enable the claimed arrangement of a carrier moiety-a linker moiety-and a peptide. Furthermore, Li does not enable the claimed combination for improved bioavailability or enhanced pharmacologic properties. As such, Li does not anticipate the present invention and is not a proper 102(b) reference.

Therefore, Applicant respectfully requests that Examiner withdraw this grounds for rejection.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

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**CONCLUSION**

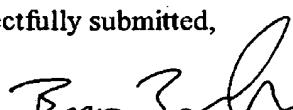
Applicant honestly believes that all aspects of the present Office Action have been sufficiently addressed and submits that the present application is now in condition for allowance, and notice to that effect is respectfully requested.

If the Examiner believes that a telephone conference with Applicants' attorneys would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Applicant believes that no fees are associated with entry of the current response. However, in the event that any fee has been inadvertently overlooked and is required, Commissioner is hereby authorized to charge any required fee or credit any overpayment to Deposit Account No. 50-3569.

Respectfully submitted,

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